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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,442	05/31/2000	CHOUNG U. KIM	237.US	9379

7590 01/06/2003  
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EXAMINER
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WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/555,442

Applicant(s)

KIM ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This action is in response to Applicants' amendment filed 6-05-02. Claim 35 is pending in this application.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Bischofberger et al., WO 96/26933.

Applicant claims cyclohexene carboxylates as neuraminidase inhibitors. Bischofberger et al. teach cyclohexene carboxylates which are neuraminidase inhibitors and intermediates useful in preparing neuraminidase inhibitors. Bischofberger et al. teach the instant compounds in page 248, scheme 45, compound 345 and page 250, lines 23-24, compound 500.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bischofberger et al., WO 96/26933.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicant claims cyclohexene carboxylates as neuraminidase inhibitors.

Bischofberger et al. teach cyclohexene carboxylates which are neuraminidase inhibitors and intermediates used to prepare neuraminidase inhibitors. Bischofberger et al. teach compounds (intermediates) which are similar to the instant compounds in page 195, compounds 1 and 22. Bischofberger et al. teach compounds which are similar to the instant compounds when, in the instant compounds,  $R^8$  is  $-OH$  or  $-OCH_2CH_3$ .

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art and the instant claims is that the prior art teaches species examples of the instant compounds (see the 102 compounds supra) as well as homologs of the instant compounds. Prior art compounds 1 and 22 both contain a  $-CO_2CH_3$  group, while in the instant compounds, the corresponding group is  $-CO_2CH_2CH_3$ . Therefore, in addition to teaching species examples of the instant compounds (see the 102 species supra), Bischofberger et al. teach compounds that differ from the instant compounds by a methyl group.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

To those skilled in chemical art, one homolog is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of a series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The motivation to prepare the instant compounds is in the expectation of obtaining compounds which are neuraminidase inhibitors and intermediates used in preparing neuraminidase inhibitors. Further motivation is

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provided by the species examples in Bischofberger et al. which have been identified in the rejection under 35 U.S.C. 102, supra.

### ***Response to Arguments***

Applicant's arguments filed 6-05-02 have been fully considered but they are not persuasive. Regarding the rejection under 35 U.S.C. 102, Applicants submit that the Bischofberger et al. compounds are methyl esters and the present compounds are ethyl esters. Applicants will note that in Bischofberger et al., both compound 345 on page 248, and compound 500 on page 250 contain a  $-\text{CO}_2\text{CH}_2\text{CH}_3$  substituent on the cyclohexene ring. Therefore, both compounds 345 and 500 of Bischofberger et al. are ethyl esters.

Regarding the rejection under 35 U.S.C. 103, the reasons given supra for the 102 rejection are applicable. Applicant argues that the Bischofberger compounds are methyl esters and the present compounds are ethyl esters. However, the Examiner identified homologs in the 103 rejection only to indicate that in addition to teaching 102 species of the instant claims, i.e. ethyl esters, Bischofberger et al. also teach homologs (methyl esters) of the instant claims.

Applicants respectfully suggest that the Office has not identified a reference which motivates the selection of ethyl among all the possible ester or other prodrugs for the active carboxylic acid. However, to those skilled in chemical art, one homolog is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of a series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The motivation to

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prepare the instant compounds is in the expectation of obtaining compounds which are neuraminidase inhibitors and intermediates used in preparing neuraminidase inhibitors. Further motivation is provided by the species examples in Bischofberger et al. which have been identified in the rejection under 35 U.S.C. 102, supra.

Regarding the objection to the abstract, it is requested that Applicants submit a copy of the abstract on a separate sheet of paper.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial

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fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



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Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

December 31, 2002

A handwritten signature in cursive script that reads "Alan L. Rotman".

ALAN L. ROTMAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600